METHOD FOR ABLATING WITH NEEDLE ELECTRODE

FIELD OF THE INVENTION

This invention relates to methods for enhancing ablation by infusing a conductive fluid through a needle electrode.

BACKGROUND OF THE INVENTION

Radiofrequency (RF) ablation of cardiac and other tissue is a well known method for creating thermal injury lesions at the tip of an electrode. Radiofrequency current is delivered between a skin (ground) patch and the electrode. Electrical resistance at the electrode-tissue interface results in direct resistive heating of a small area, the size of which depends upon the size of the electrode, electrode tissue contact, and current (density). See Avitall B, Helms R. Determinants or Radiofrequency-Induced Lesion Size in Huang SKS, Wilber DJ (eds.): Radiofrequency Catheter Ablation of Cardiac Arrhythmias: Basic Concepts and Clinical Applications, 2nd ed. Armonk, NY, Futura Publishing Company, Inc., 2000: 47-80. Further tissue heating results from conduction of heat within the tissue to a larger zone. Tissue heated beyond a threshold of approximately 50-55°C is irreversibly injured (ablated). See Nath S, and Haines DE. Pathophysiology of Lesion Formation by Radiofrequency Catheter Ablation, in Huang SKS, Wilber DJ (eds.): Radiofrequency Catheter Ablation of Cardiac Arrhythmias: Basic Concepts and Clinical Applications, 2nd ed. Armonk, NY, Futura Publishing Company, Inc., 2000: 26-28.

Resistive heating is caused by energy absorption due to electrical resistance. Energy absorption is related to the square of current density and inversely with tissue conductivity. Current density varies with conductivity and voltage and inversely with the square of radius from the ablating electrode. Therefore, energy absorption varies with conductivity, the square of applied voltage, and inversely with the fourth power of radius from the electrode. Resistive heating, therefore, is most heavily influenced by radius, and penetrates a very small distance from the ablating electrode. The rest of the lesion is created by thermal conduction from the area of resistive heating. See Lin J, Physical Aspects of Radiofrequency Ablation,

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in Huang SKS, Wilber DJ (eds.): Radiofrequency Catheter Ablation of Cardiac Arrhythmias: Basic Concepts and Clinical Applications, 2nd ed. Armonk, NY, Futura Publishing Company, Inc., 2000: 14-17. This imposes a limit on the size of ablation lesions that can be delivered from a surface electrode.

Theoretical methods to increase lesion size would include increasing electrode diameter, increasing the area of electrode contact with tissue, increasing tissue conductivity and penetrating the tissue to achieve greater depth and increase the area of contact, and delivering RF until maximal lesion size has been achieved (60-120 seconds for full maturation).

The electrode can be introduced to the tissue of interest directly (for superficial/skin structures), surgically, endoscopically, laparoscopically or using percutaneous transvascular (catheter-based) access. Catheter ablation is a well-described and commonly performed method by which many cardiac arrhythmias are treated. See Miller J M, Zipes D P. Management of the Patient with Cardiac Arrhythmias. In Braunwald E, Zipes D, Libby P (eds): Heart Disease: A Textbook of Cardiovascular Medicine, 6th Ed. Philadelphia, PA, W.B. Saunders Company, 2001: p742-752. Needle electrodes have been described for percutaneous or endoscopic ablation of solid-organ tumours, lung tumours, and abnormal neurologic structures. See, for example, McGahan J P, Schneider P, Brock J M, Tesluk H. Treatment of Liver Tumors by Percutaneous Radiofrequency Electrocautery. Seminars in Interventional Radiology 1993; 10: 143-149; Rossi S, Fornari F, Buscarini L. Percutaneous Ultrasound-Guided Radiofrequency Electrocautery for the Treatment of Small Hepatocellular Carcinoma. J Intervent Radiol 1993; 8: 97-103; and Livraghi T, Goldberg S N, Lazzaroni S, Meloni F, Monti F, Solbiati L. Saline-enhanced RF tissue ablation in the treatment of liver Metastases. Radiology 1995; 197(P): 140 (abstr)].

Catheter ablation is sometimes limited by insufficient lesion size. See de Bakker J M T, van Capelle F J L, Janse M J et al. Macroreentry in the infarcted human heart: mechanism of ventricular tacycardias with a "focal" activation pattern. J Am Coll Cardiol 1991; 18:1005-1014; Kaltenbrunner W, Cardinal R, Dubuc M et al. Epicardial and endocardial

mapping of ventricular tachycardia in patients with myocardial infarction. Is the origin of the tachycardia always subendocardially localized? Circulation 1991; 84: 1058-1071. Stevenson W G, Friedman P L, Sager P T et al. Exploring postinfarction reentrant ventricular tachycardia with entrainment mapping. J Am coll Cardiol 1997; 29: 1180-1189. Ablation of tissue from an endovascular approach results not only in heating of tissue, but of heating of the electrode. When the electrode reaches critical temperatures, denaturation of blood proteins causes formation of a high resistance coagulum that limits current delivery. Within tissue, overheating can cause evaporation of tissue or blood water and steam bubble formation that can "explode" through the myocardial wall (steam "pops") with risk of uncontrolled tissue destruction or undesirable perforation of bodily structures. In cardiac ablation, clinical success is sometimes hampered by inadequate lesion depth and transverse diameter even when using catheters with active cooling of the tip. See Soejima K, Delacretaz E, Suzuki M et al. Saline-cooled versus standard radiofrequency catheter ablation for infarct-related ventricular tachycardias. Circulation 2001; 103:1858-1862. Theoretical solutions have included increasing the electrode size (increasing contact surface and increasing convective cooling by blood flow), improving electrode-tissue contact, actively cooling the electrode with fluid infusion, changing the material composition of the electrode to improve current delivery to tissue, and pulsing current delivery to allow intermittent cooling. Needle electrodes improve contact with tissue and allow deep penetration of current delivery to areas of interest. Ablation may still be hampered by the small surface area of the needle electrode such that heating occurs at low power, and small lesions are created. Accordingly, a need exists for a method for creating improved lesions.

SUMMARY OF THE INVENTION

The invention concerns a novel method for endovascular percutaneous ablation of mammalian tissue, including cardiac tissue. This invention is useful for destroying abnormal cardiac tissue such as myocardial reentry circuits causing arrhythmias, hypertrophic cardiomyopathy causing flow obstruction, or other tissues which may be approached

endovascularly. A theoretic increase in the effective size of the electrode can be achieved by delivering conductive fluid through the needle. The fluid infiltrates the interstitium of the tissue of interest, and conducts current rapidly over a greater volume of tissue, creating a larger area of resistive heating, with a significantly larger surface area, and a consequently significantly larger volume of tissue heated by conductive heating.

In one embodiment, the invention is directed to a method for ablating tissue in or around the heart to create an enhanced lesion. The distal end of a catheter including a needle electrode at its distal end is introduced into the heart. The distal end of the needle electrode is introduced into the tissue. An electrically-conductive fluid is infused through the needle electrode and into the tissue. The tissue is ablated after and/or during introduction of the fluid into the tissue. The fluid conducts ablation energy within the tissue to create a larger lesion than would be created without the introduction of the fluid.

DESCRIPTION OF THE DRAWINGS

These and other features and advantages of the present invention will be better understood by reference to the following detailed description when considered in conjunction with the accompanying drawings wherein:

FIG. 1 is a side plan view of a catheter according to the present invention;

FIG. 2 is a side cross-sectional view of the proximal shaft, including the junction between the proximal shaft and the distal shaft;

FIG. 3 is a side cross-sectional view of the distal shaft showing the arrangement of the electromagnetic mapping sensor, needle electrode and tip electrode;

FIG. 4 is an end cross-sectional view of the distal shaft shown in FIG. 3 along line 4-4;

FIG. 5 is an end cross-sectional view of the tip electrode shown in FIG. 3 along line 5-5;

FIG. 6 is an enlarged view of the needle electrode assembly shown in FIG. 3;

FIG. 7 is an enlarged side cross-sectional view of the thermocouple mounted in the needle electrode assembly shown in FIG. 3;

FIG. 8 is a side cross-sectional view of the needle control handle where the needle is in a retracted position;

FIG. 9 is a graph showing the presence of pops versus power delivered to tissue *in vitro* using a catheter having a needle electrode as described in Example 1;

FIG. 10 is a graph showing maximum lesion width by power and duration for lesions created *in vitro* using a catheter having a needle electrode as described in Example 1;

FIG. 11 is a graph showing lesion cross-sectional area by depth for lesions created *in vivo* using a catheter having a needle electrode as described in Example 2;

FIG. 12 is a graph showing impedance during infusion of ionic solution through the needle electrode *in vitro* as described in Example 3;

FIG. 13 is a graph showing lesion diameter over time of ablation for lesions created using a needle electrode with saline infusion *in vitro* as described in Example 3; and

FIG. 14 is a graph showing lesion cross-sectional area versus depth for lesions created using a needle electrode with saline infusion *in vivo* as described in Example 4.

DETAILED DESCRIPTION

In one embodiment of the invention, there is provided a catheter particularly useful for ablating tissue in the heart. As shown in FIG. 1, the catheter comprises an elongated proximal shaft **10** having a proximal shaft **12** and a distal shaft **14**. A deflection control handle **16** is mounted at the proximal end of the proximal shaft **12**, and a needle control handle **17** is attached indirectly to the proximal shaft proximal to the deflection control handle.

With reference to Figure 2, the proximal shaft **12** comprises a single, central or axial lumen **18**. The proximal shaft **12** is flexible, i.e., bendable, but substantially non-compressible along its length. The proximal shaft **12** may be of any suitable construction and made of any suitable material. A presently preferred construction comprises an outer wall **20** made of a

polyurethane or nylon. The outer wall **20** comprises an imbedded braided mesh (not shown) of stainless steel or the like to increase torsional stiffness of the proximal shaft **12** so that, when the deflection control handle **16** is rotated, the distal shaft **14** will rotate in a corresponding manner. The outer diameter of the proximal shaft **12** is not critical, but is preferably no more than about 8 French. Likewise the thickness of the outer wall **20** is not critical.

As shown in FIGs. 2 to 4, the distal shaft **14** comprises a short section of tubing **19** having four lumens, namely, a puller wire lumen **22**, an infusion lumen **24**, a lead wire lumen **26** and a sensor cable lumen **28**. The tubing **19** is made of a suitable non-toxic material which is preferably more flexible than the proximal shaft **12**. A presently preferred material for the tubing **19** is braided polyurethane, i.e., polyurethane with an embedded mesh of braided stainless steel or the like. The outer diameter of the distal shaft **14**, like that of the proximal shaft **12**, is preferably no greater than about 8 French. The size of the lumens is not critical. In a particularly preferred embodiment, the distal shaft **14** has an outer diameter of about 0.096 inch, the infusion lumen **24** has a diameter of about 0.044 inch, and the puller wire lumen **22**, lead wire lumen **26** and sensor cable lumen **28** each have a diameter of about 0.022 inch.

A preferred means for attaching the proximal shaft **12** to the distal shaft **14** is illustrated in FIG. 2. The proximal end of the distal shaft **14** comprises an outer circumferential notch **30** that receives the inner surface of the outer wall **20** of the proximal shaft **12**. The distal shaft **14** and proximal shaft **12** are attached by glue or the like.

With reference to FIGs. 3 and 5, mounted at the distal end of the distal shaft **14** is a tip electrode **32**. For clarity, FIG. 3 only shows two of the four lumens of the distal shaft **14**. Preferably the tip electrode **32** has a diameter about the same as the outer diameter of the tubing **19**. The tip electrode **32** is connected to the tubing **19** by a plastic housing **34**, preferably made of polyetheretherketone (PEEK). The proximal end of the tip electrode **32** is notched circumferentially and fits inside the distal end of the plastic housing **34** and is bonded to the housing by polyurethane glue or the like. The proximal end of the plastic

housing **34** is bonded with polyurethane glue or the like to the distal end of the tubing **19** of the distal shaft **14**. Alternatively, the tip electrode **32** can be mounted directly to the distal end of the flexible tubing **19** of the distal shaft **14**.

Mounted on the distal end of the plastic housing **34** is a ring electrode **38**. The ring electrode **38** is slid over the plastic housing **34** and fixed in place by glue or the like. If desired, additional ring electrodes may be used and can be positioned over the plastic housing **34** and/or over the flexible tubing **19** of the distal shaft **14**.

The tip electrode **32** and ring electrode **38** are each connected to a separate electrode lead wire **40**. The electrode lead wires **40**, which each include an insulating coating, extend through the lead wire lumen **26** of distal shaft **14**, the proximal shaft **12**, and the deflection control handle **16**, and terminate at their proximal end in an input jack (not shown) that may be plugged into an appropriate monitor (not shown). In the depicted embodiment, the portion of the electrode lead wires **40** extending through the proximal shaft **12** and deflection control handle **16** are enclosed within a protective sheath **42**.

The electrode lead wires **40** are attached to the tip electrode **32** and ring electrode **38** by any conventional technique. Connection of an electrode lead wire **40** to the tip electrode **32** or ring electrode **38** is preferably accomplished by welding the electrode lead wire's distal end, which is stripped of its insulative coating, to the corresponding tip electrode or ring electrode.

A puller wire **44** is provided for deflection of the distal shaft **14**. The puller wire **44** is anchored at its proximal end to the deflection control handle **16** and anchored at its distal end to the distal shaft **14**, which . The puller wire **44** is made of any suitable metal, such as stainless steel or Nitinol, and is preferably coated with Teflon® or the like. The coating imparts lubricity to the puller wire **44**. The puller wire **44** preferably has a diameter ranging from about 0.006 to about 0.010 inches.

A compression coil **43** extends from the proximal end of the proximal shaft **12** to the proximal end of the distal shaft **14**. The compression coil **43** is made of any suitable metal, preferably stainless steel. The compression coil **43** is tightly wound on itself to provide

flexibility, i.e., bending, but to resist compression. The inner diameter of the compression coil **43** is preferably slightly larger than the diameter of the puller wire **44**. For example, when the puller wire **44** has a diameter of about 0.007 inches, the compression coil **43** preferably has an inner diameter of about 0.008 inches. The Teflon® coating on the puller wire **44** allows it to slide freely within the compression coil **43**. Along its length, the outer surface of the compression coil **43** is covered by a flexible, non-conductive sheath **49** to prevent contact between the compression coil **43** and any of the other components within the proximal shaft **12**. A non-conductive sheath **49** made of polyimide tubing is presently preferred. As shown in FIG. 2, the compression coil **43** is anchored at its proximal end to the proximal end of the proximal shaft **12** by glue to form a glue joint **50** and at its distal end to the distal shaft **14** in the puller wire lumen **22** by glue to form a glue joint **52**, but other arrangements are contemplated within the invention.

The puller wire **44** extends into the puller wire lumen **22** of the distal shaft **14**. In the depicted embodiment, the puller wire **44** is anchored in a first blind hole **54** of the tip electrode **32**. Preferably, a ferrule **41**, made of stainless steel or the like, is crimped onto the distal end of the puller wire **44** to add thickness to the puller wire. The ferrule **41** is then attached to the inside of the first blind hole **54** of the tip electrode **32** with solder or the like. Alternatively, the puller wire **44** can be anchored to the sidewall of the distal shaft **14**. Within the distal shaft **14**, the puller wire **44** extends through into a plastic, preferably Teflon®, sheath **58**, which prevents the puller wire **44** from cutting into the wall of the distal shaft when the distal shaft is deflected.

Longitudinal movement of the puller wire **44** relative to the proximal shaft **12**, which results in deflection of the distal shaft **14**, is accomplished by suitable manipulation of the deflection control handle **16**. Examples of suitable control handles for use in the present invention are disclosed, for example, in U.S. Patent Nos. Re 34,502, 5,897,529 and 6,575,931, the entire disclosures of which are incorporated herein by reference. Other control handles capable of affecting longitudinal movement of the puller wire relative to the catheter body can be used in the invention.

If desired, the catheter can include two or more puller wires (not shown) to enhance the ability to manipulate the distal shaft **14**. In such an embodiment, a second puller wire and a surrounding second compression coil extend through the proximal shaft **12** and into separate off-axis lumens (not shown) in the distal shaft. Suitable deflection control handles for use with a catheter having more than one puller wire are described in U.S. Patent Nos. 6,123,699, 6,171,277, and 6,183,463, the disclosures of which are incorporated herein by reference.

As shown in FIGs. 3 and 6, a needle electrode assembly **46** is provided within the catheter. The needle electrode assembly **46** is used to ablate tissue while simultaneously injecting saline or other fluid to conduct the ablation energy, thereby creating a theoretic increase in the effective size of the electrode. The needle electrode assembly **46** is extendable and retractable, and may be moved by manipulation of the needle control handle **17**, as described further below. FIG. 3 depicts the needle electrode assembly **46** in an extended position as it would be to ablate tissue. The distal end of the needle electrode assembly **46** may be withdrawn into the catheter to avoid injury, particularly during the time that the catheter is inserted through the vasculature of the body and during the time in which the catheter is removed from the body.

The needle electrode assembly **46** comprises a proximal tubing **33** joined, directly or indirectly, to a generally rigid, electrically-conductive distal tubing **35**, as shown in FIG. 3. The generally rigid nature of the distal tubing **35** allows it to pierce tissue in order to increase its effectiveness during ablation. For example, the distal tubing **35** can be formed of Nitinol (or other nickel-titanium alloy), gold, platinum, stainless steel, or an alloy thereof, and, as illustrated in FIG. 3, is preferably formed with a beveled edge **36** at the distal tip of the needle electrode assembly **46** to enhance its ability to pierce tissue. The diameter distal tubing **35** can vary, for example, from about 18 gauge to about 29 gauge, and more particularly can be about 27 gauge. If desired, the distal tubing **35** can include one or more irrigation ports in its sidewall in addition to or instead of the opening at the distal end of the distal tubing. Such

a design is described in U.S. Patent No. 6,575,931, the disclosure of which is incorporated herein by reference.

The proximal tubing **33** is preferably more flexible than the distal tubing **35** to allow the proximal tubing to bend as necessary with the flexible proximal shaft **13** of the catheter body **12**, for instance when the catheter is inserted into the vasculature of the body. The proximal tubing **33** of the needle electrode assembly **46** is preferably made of polyimide or polyether etherketone (PEEK), but can be made of any other suitable biocompatible material, such as plastic or metal.

A needle electrode lead wire **210** is electrically connected at its distal end to the electrically-conductive distal tubing **35** for supplying radio frequency energy or other suitable ablation energy to the distal tubing. The needle electrode lead wire **210** is soldered, welded or otherwise attached to the outside of the distal tubing **35**, but could be attached elsewhere to the distal tubing. The proximal end of the needle electrode lead wire **210** is attached to a suitable connector **67**, which in turn is connected to a suitable source of ablation energy (not shown).

Additionally, a temperature sensor is provided for measuring the temperature of the tissue being ablated by the needle electrode assembly **46** before, during or after ablation. Any conventional temperature sensor, e.g., a thermocouple or thermistor, may be used. In the depicted embodiment, the temperature sensor comprises a thermocouple **200** formed by an enameled wire pair. One wire of the wire pair is a copper wire **202**, e.g., a number 40 copper wire. The other wire of the wire pair is a constantan wire **204**. The wires **202** and **204** of the wire pair are electrically isolated from each other except at their distal ends, where they are twisted together, covered with a short piece of plastic tubing **206**, e.g., polyimide, and covered with epoxy, as shown in FIG. 7. The plastic tubing **206** is then glued or otherwise attached to the inside wall of the distal tubing **35** of the needle electrode assembly **46**. The proximal ends of the wires **202** and **204** extend out the proximal end of the distal tubing **35** and are attached to an appropriate connector **67** connectable to a suitable temperature monitor (not shown), as described in more detail below. In an alternative embodiment, the copper

wire **202** of the thermocouple can also be used as the lead wire for the needle electrode assembly **46**. The temperature sensor can be eliminated if desired or can be mounted in any other part of the needle assembly **46**, distal shaft **14** and/or tip electrode **32**.

The proximal tubing **33** of the needle electrode assembly **46** extends from the needle control handle **17**, through the deflection control handle **16**, through the proximal shaft **13**, and into the infusion lumen **24** of the distal shaft **14**. The proximal end of the distal tubing **35** is spaced slightly from the distal end of the proximal tubing **33** and extends through the infusion lumen **30** of the distal shaft **14**. The proximal and distal tubings **33** and **35** are mounted, preferably coaxially, within an outer plastic tube **48**. The outer plastic tube **48** can be glued or otherwise attached to the proximal and distal tubings to form a single structure that, as described below, is longitudinally moveable relative to the catheter body **12**. The outer plastic tube **48** extends through the catheter body **12** with the proximal tubing and protects the needle electrode lead wire **210** and thermocouple wires **202** and **204**, which extend between the proximal tubing **33** and outer plastic tube **48**, when the needle electrode assembly **46** is moved relative to the distal shaft **14**. The needle electrode lead wire **210** and thermocouple wires **202** and **204** extend out through a hole (not shown) in the outer plastic tube **48** within the deflection control handle **16** and are attached to appropriate connectors, as noted above.

FIG. 6 shows one arrangement for joining the outer plastic tube **48** to the proximal and distal tubings **33** and **35**. Specifically, a small piece of plastic tubing **45**, for example, polyimide tubing, is placed over the discontinuity between the proximal and distal tubings **33** and **35** and attached to the proximal and distal tubings by polyurethane glue or the like to form a single infusion passage through which saline or other fluid can pass from the proximal tubing to the distal tubing. The small piece of plastic tubing **45** helps to protect the thermocouple wires **202** and **204** and the needle electrode lead wire **210**. A small, preferably non-conductive, spacer **51** is mounted between the distal tubing **35** and the distal end of the outer plastic tube **48**, and optionally glued in place. The spacer **51** prevents bodily fluid from

entering into the distal end of the needle electrode assembly **46**. In FIG. 6, the relative sizes and positions of the tubings **33, 35, 45** and **48** are exaggerated for clarity.

In an exemplary embodiment, the proximal tubing **33** of the needle electrode assembly **46** has an inner diameter of 0.014 inch and an outer diameter of 0.016 inch. The distal tubing **35** has an inner diameter of 0.014 inch and an outer diameter of 0.018 inch and a length of about 1.0 inch. Further, the distal tubing **35** extends past the distal end of the distal shaft **14** about 14 mm. The small plastic tubing **45** has an inner diameter of 0.022 inch and an outer diameter of 0.024, the outer plastic tube **48** has an inner diameter of 0.025 inch and an outer diameter of 0.035 inch, and the plastic spacer **51** has an inner diameter of 0.017 inch and an outer diameter of 0.024 inch.

Within the proximal shaft **12** and distal shaft **14**, the needle electrode assembly **46**, comprising the proximal tubing **33**, distal tubing **35**, spacer **51**, plastic tubing **45** and outer plastic tube **48**, is slidably mounted, preferably coaxially, within a protective tube **47** that is stationary relative to the catheter body. The protective tube **47** has a distal end glued into a passage **56** that extends through the tip electrode **32**. The protective tube **47**, which is preferably made of polyimide, serves to prevent the needle electrode assembly **46** from buckling during extension and retraction of the needle electrode assembly relative to the catheter body **12**. The protective tube **47** additionally serves to provide a fluid-tight seal surrounding the needle electrode assembly **46**. Within the deflection control handle **16**, the protective tube **47** and needle electrode assembly **46** extend into a protective shaft **66**, which is preferably made of polyurethane.

Other needle electrode assembly designs are contemplated within the scope of the invention. For example, the needle electrode assembly can comprise a single electrically-conductive tube, such as a Nitinol tube, that extends from the needle control handle **17** to the distal end of the catheter. Such a design is described in U.S. Patent Application No. 09/711,648, entitled "Injection Catheter with Needle Electrode," the disclosure of which is incorporated herein by reference.

Longitudinal movement of the needle electrode assembly **46** is achieved using the needle control handle **17**. The needle electrode assembly **46** and protective tube **47** extend from the deflection control handle **16** to the needle control handle **17** within the protective shaft **66.**

As illustrated in FIG. 8, in one embodiment the needle control handle **17** comprises a generally cylindrical outer body **80** having proximal and distal ends, a piston chamber **82** extending a part of the way therethrough, and a needle passage **83** extending a part of the way therethrough. The piston chamber **82** extends from the proximal end of the handle part way into the body **80**, but does not extend out the distal end of the body. The needle passage **83**, which has a diameter less than that of the piston chamber **82**, extends from the distal end of the piston chamber to the distal end of the outer body **80**.

A piston **84**, having proximal and distal ends, is slidably mounted within the piston chamber **82**. A proximal fitting **86** is mounted in and fixedly attached to the proximal end of the piston **84**. The proximal fitting **86** includes a tubular distal region **87** that extends distally from the main body of the proximal fitting. The piston **84** has an axial passage **85** through which the proximal tubing **33** of the needle electrode assembly **46** extends, as described in more detail below. A compression spring **88** is mounted within the piston chamber **82** between the distal end of the piston **84** and the outer body **80**. The compression spring **88** can either be arranged between the piston **84** and outer body **80**, or can have one end in contact with or fixed to the piston, while the other end is in contact with or fixed to the outer body.

The proximal tubing **33**, outer plastic tube **48**, protective tube **47** and protective shaft **66** extend from the deflection control handle **16** into the distal end of the needle passage **83**, as best shown in AREA A of FIG. 8. Within the needle passage **83**, the proximal tubing **33**, outer plastic tube **48**, protective tube **47** and protective shaft **66** extend into a first metal tube **90**, which is preferably made of stainless steel. If desired, the first metal tube **90** could instead be made of a rigid plastic material. The first metal tube **90** is secured to the

outer body **80** of the needle control handle **17** by a set screw **101** or any other suitable means. The protective shaft **66** terminates at its proximal end within the first metal tube **90**.

A second metal tube **91** is provided with its distal end mounted, preferably coaxially, inside the proximal end of the first metal tube **90** and with its distal end abutting the proximal end of the protective shaft **66**. The second metal tube **91** is fixed in place relative to the first metal tube **90** by the set screw **101**. The second metal tube **91**, like the first metal tube **90**, could alternatively be made of a rigid plastic material.

The proximal end of the second metal tube **91** is mounted, preferably coaxially, around the distal end of the tubular distal region **87** of the proximal fitting **86**, with the second metal tube being longitudinally movable relative to the tubular distal region **87**. Accordingly, when the piston **84** is moved distally relative to the outer body **80**, the tubular distal region **87** moves distally into the second metal tube **91**. As shown in AREA B of FIG. 8, the proximal tubing **33** and outer plastic tube **48** extend through the second metal tube **91** and into the tubular distal region **87** of the proximal fitting **86**. The outer plastic tube **48** terminates in and is fixedly attached to the proximal fitting **86** to thereby attach the outer plastic tube, and thus the needle electrode assembly **46**, to the piston **84**. Within the proximal fitting **86**, the proximal tubing **33** extends out of the outer plastic tube **48** and into a first protective sheath **31**, as shown in AREA C of FIG. 8, and is connected to a luer connector **65**, which is connected to an irrigation pump or other suitable fluid infusion source (not shown), as is known in the art. Similarly, the needle electrode lead wire **210** and the thermocouple wires **202** and **204** extend out of the outer plastic tube **48** and into a second protective sheath **29**, as also shown in AREA C of FIG. 2, which is connected to a suitable connector **67**, such as a 10-pin electrical connector, for connecting the needle electrode lead wire to a source of ablation energy and the thermocouple wires to a suitable monitoring system.

In use, force is applied to the piston **84** to cause distal movement of the piston relative to the outer body **80**, which compresses the compression spring **88**. This movement causes the needle electrode assembly **46** to correspondingly move distally relative to the outer body

80, protective shaft **66**, protective tube **47**, proximal shaft **13**, and distal shaft **14** so that the distal tubing **35** of the needle electrode assembly extends outside the distal end of the distal shaft. When the force is removed from the piston **84**, the compression spring **88** pushes the piston proximally to its original position, thus causing the distal tubing **35** of the needle electrode assembly **46** to retract back into the distal end of the distal shaft **14**. Upon distal movement of the piston **84**, the tubular distal region **87** of the proximal fitting **86** moves distally into the second metal tube **91** to prevent the proximal tubing **33** and the outer plastic tube **48** of the needle electrode assembly **46** from buckling within the axial passage **85**.

The piston **84** further comprises a longitudinal slot **100** extending along a portion of its outer edge. A securing means **102**, such as a set screw, pin, or other locking mechanism, extends through the outer body **80** and into the longitudinal slot **100**. This design limits the distance that the piston **84** can be slid proximally out of the piston chamber **82**. When the needle electrode assembly **46** is in the retracted position, preferably the securing means **102** is at or near the distal end of the longitudinal slot **100**.

The proximal end of the piston **84** has a threaded outer surface **104**. A circular thumb control **106** is rotatably mounted on the proximal end of the piston **84**. The thumb control **106** has a threaded inner surface **108** that interacts with the threaded outer surface **104** of the piston. The thumb control **106** acts as a stop, limiting the distance that the piston **84** can be pushed into the piston chamber **82**, and thus the distance that the needle electrode assembly **46** can be extended out of the distal end of the catheter. The threaded surfaces of the thumb control **106** and piston **84** allow the thumb control to be moved closer or farther from the proximal end of the outer body **80** so that the extension distance of the needle electrode assembly **46** can be controlled by the physician. A securing means, such as a tension screw **110** is provided in the thumb control **106** to control the tension between the thumb control and piston **84**. As would be recognized by one skilled in the art, the thumb control **106** can be replaced by any other mechanism that can act as a stop for limiting the distance that the piston **84** extends into the piston chamber **82**, and it is not necessary, although it is preferred, that the stop be adjustable relative to the piston.

Additionally, a location sensor **70** is contained within the distal end of the distal shaft **14**. The location sensor **70** is used to determine the coordinates of the distal end of the catheter, for example, during mapping of electrical activity or during placement of the distal end of the catheter for ablation. In the depicted embodiment, a single location sensor **70** is mounted in the distal end of the distal shaft **14**, partly within a second blind hole **55** in the tip electrode **32** and partly within the plastic housing **34**.

The location sensor **70** is connected to a corresponding sensor cable 72. The sensor cable **72** extends through proximal shaft **12** and deflection control handle **16** and out of the proximal end of the deflection control handle within an umbilical cord (not shown) to a sensor control module (not shown) that houses a circuit board (not shown). Alternatively, the circuit board can be housed within the deflection control handle **16**, for example, as described in U.S. Patent No. 6,024,739, the disclosure of which is incorporated herein by reference. The sensor cable **72** comprises multiple wires encased within a plastic covered sheath. In the sensor control module, the wires of the sensor cable **72** are connected to the circuit board. The circuit board amplifies the signal received from the location sensor **70** and transmits it to a computer in a form understandable by the computer by means of a sensor connector at the proximal end of the sensor control module. Also, because the catheter is designed for single use only, the circuit board preferably contains an EPROM chip that shuts down the circuit board approximately twenty-four hours after the catheter has been used. This prevents the catheter, or at least the location sensor **70**, from being used twice.

Preferably the location sensor **70** is an electromagnetic location sensor. For example, the location sensor **70** may comprise a magnetic-field-responsive coil, as described in U.S. Patent No. 5,391,199, or a plurality of such coils, as described in International Publication WO 96/05758. The plurality of coils enables the six-dimensional coordinates (i.e. the three positional and the three orientational coordinates) of the location sensor **70** to be determined. Alternatively, any suitable location sensor known in the art may be used, such as electrical, magnetic or acoustic sensors. Suitable location sensors for use with the present invention are also described, for example, in U.S. Patent Nos. 5,558,091, 5,443,489, 5,480,422, 5,546,951,

and 5,568,809, International Publication Nos. WO 95/02995, WO 97/24983, and WO 98/29033, and U.S. Patent Application Serial No. 09/882,125 filed June 15, 2001, entitled "Position Sensor Having Core with High Permeability Material," the disclosures of which are incorporated herein by reference. Using this technology, the physician can visually map a heart chamber. This mapping is done by advancing the distal shaft **14** into a heart chamber until contact is made with the heart wall. This position is recorded and saved. The distal shaft **14** is then moved to another position in contact with the heart wall and again the position is recorded and saved.

The electromagnetic mapping sensor **70** can be used alone or, more preferably, in combination with the tip electrode **32** and/or ring electrode **38**. By combining the electromagnetic sensor **70** and electrodes **32** and **38**, a physician can simultaneously map the contours or shape of the heart chamber, the electrical activity of the heart, and the extent of displacement of the catheter.

It is understood that, while it is preferred to include both electrophysiology electrodes (such as the tip electrode **32** and ring electrode **38**) and an electromagnetic sensor in the distal shaft **14**, it is not necessary to include both. For example, an ablation catheter having an electromagnetic sensor but no electrophysiology electrodes may be used in combination with a separate mapping catheter system. A preferred mapping system includes a catheter comprising multiple electrodes and an electromagnetic sensor, such as the NOGA-STAR catheter marketed by Biosense Webster, Inc., and means for monitoring and displaying the signals received from the electrodes and electromagnetic sensor, such as the Biosense-NOGA system, also marketed by Biosense Webster, Inc.

The catheters in accordance with the present invention are particularly suitable for ablating large, deep lesions in heart tissue. In operation, the distal end of the catheter is inserted into a vein or artery and advanced into the heart. To assist in positioning the distal shaft **14** of the catheter at a desired position within the heart, the puller wire **50** and deflection control handle **16** are used to deflect the distal shaft **14**. Once the distal shaft **14** has been positioned at or near the desired location of the heart tissue, and preferably arranged

generally perpendicular to the heart tissue, the distal end of the needle electrode assembly **46** is advanced distally, using the needle control handle **17,** out of the distal end of the catheter and into the adjacent heart tissue.

The depth to which the distal end of the needle electrode assembly **46** is advanced into the heart tissue can vary depending on the desired size of the lesion to be produced. For example, the depth of the needle penetration can range from about 2 to about 30 mm, more particularly from about 3 to about 20 mm, still more particularly from about 4 to about 10 mm, even more particularly from about 5 to about 7 mm. The deeper the needle is advanced, the more needle surface area that is provided for ablation, but the greater the risk of perforation. The needle is preferably advanced a sufficient distance so that fluid infused through the needle goes into the heart tissue.

Fluid is then infused through the needle ablation assembly **46**, before and/or during ablation, to enhance the ablation by serving as a virtual electrode. The fluid used should be biologically acceptable and should be able to conduct ablation energy from the needle electrode to the heart tissue. Preferably the fluid used is saline having a salt content ranging from about 0.3 to about 4 wt%, more particularly from about 0.5 to about 3 wt%, still more particularly from about 0.9 to about 2.5 wt%, even more particularly from about 0.9 to about 1.5 or 2 wt%.

If desired, the saline or other fluid being infused through can include a radiographic contrast agent, preferably comprising an iodinated compound, such as an iodinated contrast with diatrizoate salt with meglumine and sodium or an ioxaglate salt with meglumine and sodium; or a nonionic contrast with iohexol, iopamidol, iopromide, and/or ioversol. If used, the amount of contrast media present in the fluid can vary as desired, and can range, for example, from about 5 to about 50%, more particularly from about 10 to about 30%, still more particularly from about 10 to about 20%. The contrast agent permits the electrophysiologist to view the relative location of the distal end of the needle electrode, thereby providing both evidence concerning adequate tissue penetration and reassurance that the needle electrode has not penetrated all the way through the myocardium into the

pericardium. The contrast agent also gives the electrophysiologist an indication of the approximate size and shape of the lesion that will be created.

The flowrate of the fluid through the needle ablation assembly and the duration of infusion can vary depending on the desired lesion size and the size of the distal tubing of the needle, i.e., that part of the needle introduced into the tissue. For example, saline or other fluid can be infused through the needle ablation assembly into the heart tissue at a rate ranging from about 0.3 to about 5 ml/min, more particularly from about 0.3 to about 3 ml/min, still more particularly from about 0.8 to about 2.5 ml/min, still more particularly from about 1 to about 2 ml/min. If infusing prior to ablation, preferably the fluid is not infused for more than a minute prior to beginning ablation.

Ablation energy, preferably radio frequency, is then applied to the distal tubing **35** of the ablation needle assembly **46** though the needle electrode lead wire **210**. The amount of energy can vary depending on the desired lesion size, and can be, for example, up to about 100 watts, more particularly up to about 70 watts, still more particularly from about 20 to about 50 watts, even more particularly from about 30 to about 40 watts. The duration of the ablation, i.e., the duration that the radio frequency energy is delivered to the needle electrode and thus to an area of tissue through the needle electrode and through the saline or other fluid passing through the needle electrode, can also vary on the size of the desired lesion. It has been found that substantial lesions can be created with a duration of ablation that need not be significantly longer than about 120 seconds. Preferably the duration of ablation is at least about 15 seconds, more preferably at least about 30 seconds, and may last as long as 60 seconds, 90 seconds or more.

If the needle electrode is used for ablation without prior or simultaneous fluid of an ionically-conductive fluid, the lesion size will not be as large, and the amount of power cannot be as high as with the infusion of the fluid. For example, for a needle electrode without saline infusion, the power should not exceed about 5 to 10 watts to avoid charring, whereas much more power can be delivered with fluid infusion without significant charring. The saline or other fluid permeates between the muscle fibers and spreads out from the

needle electrode puncture site. As a result, the electrical resistance is spread over a larger area. The resulting lesion is typically generally spherically-shaped.

If desired, a surface lesion can be burned with the tip electrode **32** before, during and/or after a lesion is created with the needle electrode to increase the size of the endocardial portion of the ablation and create a more bullet-shaped lesion. In an alternative method, the needle electrode is used only to infuse saline into the heart tissue, and the tip electrode is the used to ablate a burn from the tissue surface.

Impedance can be measured through the needle electrode, for example, by the radio frequency energy generator, as is generally known in the art. The impedance measurement can be used to vary the flow rate of the saline or other fluid, the amount of power delivered, and/or the time that the fluid is infused and/or the power delivered. If desired, a feedback control loop can be created.

Similarly, the temperature of the tissue can be indirectly measured by measuring the temperature of the distal tubing **35** of the ablation needle assembly **46** using the temperature sensor mounted in the distal tubing. The temperature measurement can similarly be used to vary the flow rate of the saline or other fluid, the amount of power delivered, and/or the time that the fluid is infused and/or the power delivered, and a feedback control loop can be created. Preferably the temperature of the distal tubing **35** ranges from about 35 to about 90°C, more preferably from about 45 to about 80°C, still more preferably from about 55 to 70°C. If desired, a portion of the distal tubing **35** of the needle ablation assembly **46** can be coated or covered with an insulating material. Preferably the distal end region, e.g., about 1 to about 30 mm, more particularly from about 2 to about 20 mm, even more particularly from about 3 to about 12 mm, of the distal tubing **35** is exposed, i.e., remains electrically conductive, and a region proximal to the distal end region is covered with the insulating material. With this design, ablation energy can be delivered to the tissue without being delivered at the endocardial surface to avoid overheating at the endocardial surface, which can cause clotting.

The distal tubing **35** of the needle ablation assembly **46**, the tip electrode **32** and/or any ring electrodes **38** can be used to measure and record electrical activity. In particular, the electrical activity can be measured before ablation to confirm that the tissue should be ablation and/or after ablation to confirm that the ablation had the desired effect on the tissue, e.g., that the electrical activity in that tissue has been changed or eliminated. The distal tubing **35** of the needle ablation assembly **46** and/or the tip electrode **32** can also be used for pacing, for example, to determine whether tissue is viable before ablating and/or to determine whether the ablation had the desired effect.

EXAMPLES

The following examples show suitable ablation methods according to the invention. Experiments were conducted *in vitro* using bovine myocardium, and *in vivo* using swine and goats.

Example 1 - *In Vitro* Needle Ablation Studies

Feasibility studies of delivery of radiofrequency (RF) ablative energy to tissue using a catheter having a needle electrode were carried out using bovine myocardium in room temperature 0.9% NaCl solution. RF energy was delivered using a Stockert 70 RF generator. Tissue overheating and pops occurred at relatively low power outputs. Steam pops tended to occur when power was higher, but this did not reach statistical significance ($p=0.183$). See FIG. 9. It was determined that lesions could be created and had depth to the full extent of needle penetration, but lesion diameter was limited by impedance rises and tissue overheating, with subsequent current limitation. RF lesion diameter increased with average power delivered and with maximum power delivered. Lesion size plateaued after 30 to 60 seconds of RF application, and increased with power delivered, reaching a plateau at 8 to 10 Watts. See FIG. 10. Lesion depth was limited only by needle length.

Example 2 - *In Vivo* Needle Ablation Studies

In vivo temperature-controlled needle ablation lesions were performed in anaesthetized swine. The catheter was introduced into femoral vessels and navigated using fluoroscopy and electroanatomic mapping. The distal end was placed in contact with and perpendicular to the endocardium. The needle electrode was extended 10 mm, and RF energy (500 kHz, Stockert-70 RF Generator, Freiburg, Germany) was delivered between the needle electrode and a skin electrode for 120 second applications. Temperature was monitored using the thermocouple within the needle electrode, and power was titrated manually to maintain temperature at or below 90° C. Control lesions were created with a standard ablation catheter under temperature control titrated to maintain tip temperature at or below 60° C for 120 second applications. Thirteen needle ablations and nine control lesions were available for analysis. The animal was sacrificed, and the lesions were identified and excised. They were formalin-fixed and serially sectioned from the endocardium and digitally imaged for quantitative analysis. Needle ablation lesions had a characteristic appearance with minimal endocardial disruption, and a small circular area of pallor. The cut surfaces revealed a long narrow lesion extending the full length of the needle track with a uniform diameter. Control lesions had an ovoid area of pallor on the surface, slight widening within the first 2 mm of depth, and then rapid tapering. Needle lesions were significantly deeper than control lesions but of smaller volume. See Table 1, below, and FIG. 11.

Table 1: *In Vivo* Needle Ablation Results

	Needle Lesions	Control Lesions	
Mean Depth	10.2 ± 0.8 mm	5.7 ± 0.4 mm	$p < 0.001$
Likelihood Transmural	77%	11%	$p = 0.008$
Mean Volume	175 ± 18 mm^3	358 ± 56 mm^3	$p = 0.02$
Maximal Diameter (mean)	7 ± 0.4 mm	12 ± 0.7 mm	$p < 0.001$

Example 3 - *In Vitro* Needle Infusion Ablation Studies

In order to increase lesion dimension, the size of the area of resistive heating needed to be increased. Infusion of ionic solution through the needle electrode into the tissue of interest increased the size of the virtual electrode, increasing conductance in the area immediately surrounding the ablating needle electrode. This shifts the site of the steepest gradient of resistance, and thus the zone of resistive heating farther from the electrode and creates a larger area of resistive heating, and consequently a larger area of conductive heating. Bovine myocardium strips were immersed in ionic solution at room temperature. The needle electrode was deployed within the tissue, and 0.9% NaCl solution was infused at 1 mL/minute and 2 mL/minute with serial observations of the impedance recorded. The initial impedance fell by approximately 20 ohms during the first 20 seconds of infusion and then relatively plateaued during the rest of 120 seconds of infusion. See FIG. 12.

Further studies demonstrated *in vitro* that with a preinjection of 0.9% NaCl of up to 60 seconds at 1 mL/min, and with continued 1 mL/min infusion during RF and power set at 10W, lesion size plateaued at approximately 120 seconds. Lesions created in this manner were significantly larger than those created without saline infusion. See FIG. 13.

Example 4 - *In Vivo* Needle Infusion Ablation Studies

In ten anaesthetized swine, the left ventricle was entered using the catheter via the femoral artery and directed using electroanatomic mapping and fluoroscopy. The distal end of the catheter was positioned perpendicularly to the endocardial surface, and the needle electrode was advanced 5 to 7 mm into the myocardium. 0.9% NaCl solution was infused at 1 mL/min intramyocardially for 60 seconds, and RF was delivered via the needle electrode for 120 seconds during ongoing infusion. Power was titrated to 30 to 40 Watts, adjusted to avoid impedance rises. At the end of the procedure, the heart was excised, and the lesions were identified, excised and formalin fixed. They were then serially sectioned from the endocardium and digitally imaged for quantitative analysis. Lesion volume was calculated. Lesions were compared to standard endocardial ablation lesions created under power control,

titrated to achieve a 10 ohm impedance fall using a 4 mm tip catheter. Needle infusion ablation lesions were significantly deeper than controls, more likely to be transmural and had significantly larger volumes and cross-sectional areas at each millimeter of depth beyond the endocardium. See Table 2 and FIG. 14.

Table 2: Saline Needle Infusion *In Vivo*

	Needle/Infusion	Control	
Mean Depth	13 ± 2 mm	5 ± 1 mm	$P<0.001$
Likelihood Transmural	41 %	11 %	$P = 0.03$
Volume	$1600 \pm 100\ mm^3$	$240 \pm 40\ mm^3$	$P < 0.001$

The preceding description has been presented with reference to presently preferred embodiments of the invention. Workers skilled in the art and technology to which this invention pertains will appreciate that alterations and changes in the described structure may be practiced without meaningful departing from the principal, spirit and scope of this invention. For example, the tip electrode can be eliminated if desired. The location sensor could also be eliminated, in which case another mapping method, such as ultrasound, could optionally be used to determine the location of the catheter. Accordingly, the foregoing description should not be read as pertaining only to the precise structures and methods described and illustrated in the accompanying drawings, but rather should be read consistent with and as support to the following claims which are to have their fullest and fair scope.